



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration

[Docket No. FDA-2012-N-0012]

Office of the Commissioner of Food and Drugs; Delegation of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

Notice is hereby given that I have delegated to the Commissioner of Food and Drugs (the Commissioner) certain authority added to the Public Health Service Act by section 801 of Public Law 110-85, the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 282(j)), pertaining to the expansion of the Clinical Trial Registry and Results Data Bank described therein. Specifically, the Commissioner is delegated the following authority:

- Section 402(j)(5)(C)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(5)(C)(ii)) -- To determine that any clinical trial information was not submitted as required under 42 U.S.C. 282(j) or was submitted but is false or misleading in any particular and to notify the responsible party and give such party an opportunity to remedy non-compliance by submitting required revised clinical trial information not later than 30 days after such notification.

This authority may be redelegated. This delegation will be exercised in accordance with the Department of Health and Human Services' applicable policies, procedures, guidelines, and regulations.

I ratify and affirm any actions taken by the Commissioner or her subordinates that involved the exercise of the authority delegated herein prior to the effective date of this delegation. This delegation is effective upon date of signature.

Date: September 5, 2012.

Kathleen Sebelius,

Secretary of Health and Human Services.

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